

AMENDMENTS TO THE CLAIMS

Listing of Claims:

1. (Currently Amended) A pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and fluticasone or a pharmaceutically acceptable ester thereof ~~a steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, which contains the fluticasone or a pharmaceutically acceptable ester thereof~~ in an amount from about 50 micrograms/ml to about 5 mg/ml of the formulation.
2. (Original) A pharmaceutical formulation according to claim 1, wherein said azelastine is present as azelastine hydrochloride.
3. (Canceled)
4. (Currently Amended) A formulation according to ~~claim 3~~ claim 1, wherein the ~~steroid pharmaceutically acceptable ester is beclomethasone propionate, mometasone furoate, mometasone furoate monohydrate, fluticasone propionate or fluticasone valerate.~~
5. (Canceled)
6. (Currently Amended) A formulation according to claim 1, wherein the formulation has a particle size of less than ~~about~~ 10 μm .

7. (Currently Amended) A formulation according to claim 1, which is a suspension containing 0.0005 to 2% (weight/weight of the formulation) of azelastine or a pharmaceutically acceptable salt of azelastine, and from 0.5 to 1.5% (weight/weight of the formulation) of fluticasone or a pharmaceutically acceptable ester thereof~~said steroid~~.

8. (Currently Amended) A formulation according to claim 7, which contains from 0.001 to 1% (weight/weight of the formulation) azelastine, or salt thereof, and from 0.5% to 1.5% (weight/weight of the formulation) fluticasone or a pharmaceutically acceptable ester thereof~~steroid~~.

9. (Previously Presented) A formulation according to claim 1, which also contains a surfactant.

10. (Original) A formulation according to claim 9, wherein the surfactant comprises a polysorbate or poloxamer surfactant.

11. (Previously Presented) A formulation according to claim 9, which contains from about 50 micrograms to about 1 milligram of surfactant per ml of the formulation.

12. (Previously Presented) A formulation according to claim 1, which also contains an isotonic agent.

13. (Original) A formulation according to claim 12, wherein the isotonic agent comprises sodium chloride, saccharose, glucose, glycerine, sorbitol or 1,2-propylene glycol.

14. (Previously Presented) A formulation according to claim 1, which also contains at least one additive selected from the group consisting of a buffer, a preservative, a suspending agent and a thickening agent.

15. (Original) A formulation according to claim 14, wherein said preservative is selected from edetic acid and its alkali salts, lower alkyl p-hydroxybenzoates, chlorhexidine, phenyl mercury borate, or benzoic acid or a salt, a quaternary ammonium compound, or sorbic acid or a salt thereof.

16. (Previously Presented) A formulation according to claim 14, wherein the suspending agent or thickening agent is selected from cellulose derivatives, gelatin, polyvinylpyrrolidone, tragacanth, ethoxose (water soluble binding and thickening agents on the basis of ethyl cellulose), alginic acid, polyvinyl alcohol, polyacrylic acid, or pectin.

17. (Previously Presented) A formulation according to claim 14, wherein the buffer comprises a citric acid-citrate buffer.

18. (Currently Amended) A formulation according to claim 14, wherein the buffer maintains the pH of the aqueous phase at from 3 to 7, preferably 4.5 to about 6.5.

19. (Previously Presented) A formulation according to claim 1, which is an aqueous suspension or solution.

20. (Previously Presented) A formulation according to claim 1, which is in the form of an aerosol, an ointment, eye drops, nasal drops, a nasal spray, an inhalation solution and other forms suitable for nasal or ocular administration.

21. (Original) A formulation according to claim 20, which is in the form of nasal drops or nasal spray.

22. (Original) A formulation according to claim 20, which is in the form of an aerosol.

23-24. (Canceled)

25. (Previously Presented) A formulation according to claim 1, which is in the form of an insufflation powder.

26. (Currently Amended) A pharmaceutical product ~~according to claim 1~~, comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided in an aerosol formulation preferably together with a propellant typically suitable for MDI delivery, and (ii) fluticasone or a pharmaceutically acceptable ester thereof ~~at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative~~

thereof, provided in an aerosol formulation preferably together with a propellant typically suitable for MDI delivery, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

27. (Previously Presented) An aerosol formulation preferably suitable for MDI delivery comprising the formulation of claim 1, together with a propellant.

28. (Currently Amended) A pharmaceutical product comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided as an insufflation powder, and (ii) fluticasone or a pharmaceutically acceptable ester thereof ~~at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof,~~ provided as an insufflation powder, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

29. (Currently Amended) An insufflation powder formulation comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and (ii) fluticasone or a pharmaceutically acceptable ester thereof ~~at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof,~~ together with a pharmaceutically acceptable carrier or excipient therefor.

30. (Currently Amended) A pharmaceutical product comprising the formulation according to claim 1, wherein (i) azelastine, or a pharmaceutically acceptable salt thereof, and (ii) ~~wherein at least one steroid is selected from the group consisting of beclomethasone, fluticasone, mometasone and or a pharmaceutically acceptable esters thereof,~~ as a combined preparation with said azelastine for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

31-34. (Canceled)

35. (Currently Amended) A pharmaceutical product comprising the pharmaceutical formulation of claim 1, wherein said azelastine is azelastine hydrochloride and said pharmaceutically acceptable estersteroid is fluticasone propionate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

36. (Currently Amended) A pharmaceutical formulation according to claim 1, wherein said azelastine is azelastine hydrochloride and said pharmaceutically acceptable estersteroid is fluticasone propionate, together with a pharmaceutically acceptable carrier or excipient therefor.

37. (Currently Amended) A pharmaceutical product comprising the pharmaceutical formulation of claim 1, wherein said azelastine is azelastine hydrochloride and said pharmaceutically acceptable estersteroid is fluticasone valerate, as a combined preparation for

simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

38. (Currently Amended) A pharmaceutical formulation according to claim 1, wherein said azelastine is azelastine hydrochloride and said pharmaceutically acceptable ester~~steroid~~ is fluticasone valerate, together with a pharmaceutically acceptable carrier or excipient therefor.

39-43. (Canceled)

44. (Currently Amended) A process of preparing a pharmaceutical product according to claim 26, which process comprises providing (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and (ii) fluticasone or a pharmaceutically acceptable ester thereof~~at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof~~, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more antihistamine and/or one or more steroid is indicated.

45. (Currently Amended) A process of preparing a pharmaceutical formulation according to claim 1, which process comprises admixing a pharmaceutically acceptable carrier or excipient with azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and fluticasone or a pharmaceutically acceptable ester thereof~~at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof~~.

46-52. (Canceled)

53. (New) A formulation according to claim 1, wherein the pharmaceutically acceptable ester is fluticasone propionate.

54. (New) A formulation according to claim 1, wherein the pharmaceutically acceptable ester is fluticasone valerate.

55. (New) A pharmaceutical product comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided as a nasal spray, and (ii) fluticasone or a pharmaceutically acceptable ester thereof, provided as a nasal spray, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

56. (New) A nasal spray formulation comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and (ii) fluticasone or a pharmaceutically acceptable ester thereof, together with a pharmaceutically acceptable carrier or excipient therefor.